EXHIBIT C

Columbia University
MAILMAN SCHOOL
OF PUBLIC HEALTH

DEPARTMENT OF BIOSTATISTICS

NFL Players Settlement Clinical Data Repository

The Data Management Unit (DMU) in the Department of Biostatistics in Columbia University's Mailman School of Public Health has more than 20 years' experience in creating state-of-the-art data management platforms for a wide range of clinical research projects, from small pilot studies to epidemiological studies to international clinical trials. Under the direction of Richard Buchsbaum, the unit serves projects throughout Columbia University, and currently hosts more than 50 active applications. DMU data systems have been certified by Columbia University Medical Center IT as secure for the storage of both research and patient care data. As part of this certification, the systems are audited regularly for security and regulatory compliance. The DMU is well-situated to create a secure, flexible, searchable data repository for clinical data generated as part of the NFL players settlement.

Creation of a shared data resource for data collected under the NFL players settlement will comprise 5 general tasks.

1. Inventory and analysis of existing information, creation of data abstraction forms, and the creation of a new, secure database for storage.
2. Abstraction of data, and entry into the new database.
3. Creation of a data mining tool, available to the public, which will provide information of the nature and extent of the data stored in the resource while maintaining confidentiality.
4. Creation and implementation of a process for requesting data from the resource, reviewing and ruling on requests, and distribution of data to approved requesters.
5. Creation of a schedule for abstraction and entry of data collected in the future.

Work will begin with an analysis of all existing information which is to be submitted to the resource. In consultation with subject matter experts, data abstraction forms will be created to collect the maximum possible information from the reports documenting each case (with the understanding that few if any individual cases will provide all data items.) The abstraction forms will allow for the digitization of information in a rigorous format which will expedite future analyses. This includes normalizing the database structure (eliminating redundancies, atomizing data elements for maximum flexibility, minimizing ambiguity), regularizing coding for categorical variables, segregation of potentially identifying information and creating surrogates as necessary, etc. A central database will be constructed to store the data from the abstraction forms. Along with the creation of the new central database, we will create a data dictionary fully documenting the structure of the new resource and the source of each data item in the source data. Finally, we will create a secure, dedicated web-based data entry interface to allow entry of the abstracted data. This interface will include a number of utilities to promote data quality (range checks for continuous variables, drop-down lists for categorical variables, inter-variable logic checks, etc.) as well as tools recording user access, updates, and other audit-trail information.

Once the new database has been created, data staff will be trained by the data center and the subject matter experts in the abstraction of data from the primary sources (reports). Upon completion of

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training, these staff will abstract the data and enter the results into the database using the web interface. These routines will be fully documented and made available for maximum transparency.

After the data have been documented and abstracted, we will create a web-based data mining tool which will allow external users to explore the nature and extent of the resources in the database without having access to actual data. This will include the ability to view the data items (columns) in the database along with descriptions of their content. Users will also be able to view summary data on individual items, including basic frequencies, distributions and simple summary statistics such as means, standard deviations, etc. Care will be taken to maintain confidentiality in the presentation of these statistics, by removing all references to counts fewer than 10 (or some other agreed-upon figure), rounding dates to years (or, again, some other agreed-upon interval), and other techniques. In cases where doing so will not violate confidentiality, users will be able to apply filters the database in order to ascertain the extent of available data for particular analyses.

In parallel with the development of the data mining tool, we will work with all stakeholders to develop a process for the distribution of data to approved researchers. This will involve an online request mechanism, through which interested researchers can describe the data they desire and the analyses they plan. We will also organize a data use committee, and establish guidelines for the evaluation of requests for data. The online system will also provide online access to descriptive materials including the data dictionary, as well as documents describing resource policies, requirements, data sharing agreement templates, etc. The web-based data request system will provide mechanisms for notifying members of the data use committee of incoming requests, allow them to request additional information or alterations to requests, and to indicate approval or rejection of requests. We will establish mechanisms for generating analysis data sets in response to approved requests, and for providing access to those data sets to approved applicants who have completed all the necessary requirements (executed data sharing agreements, etc.)

Finally, we will establish routines for the regular and efficient entry of new data into the database as it is collected over time.

Estimated budget for this proposed scope, to be executed within one (1) calendar year, totals **$180,000**, and is based on effort for DMU staff members plus associated university infrastructure costs. Approximate effort for the individual tasks described above is provided below.

1. Inventory and analysis of existing information, creation of data abstraction forms, and the creation of a new, secure database for storage: **25-30 hours**

2. Creation of a data mining tool, available to the public, which will provide information of the nature and extent of the data stored in the resource while maintaining confidentiality: **20-25 hours**

3. Creation and implementation of a process for requesting data from the resource, reviewing and ruling on requests, and distribution of data to approved requesters: **20-30 hours**

4. Creation of a schedule for abstraction and entry of data collected in the future: **TBD based on volume of data**

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5. Abstraction of data and entry into new database: **1250 hours**

Estimated budget for tasks #1-4 above totals **$30,000**. This supports staff time, training, and supervision.

Estimated budget for task #5 above totals **$147,800**. Data abstraction and entry is the largest portion of the budget, since the process is so time-consuming. From the review of the sample records provided, we have assumed that this process will take an average 15 minutes per record: some will take more time, some less, and with scheduled breaks, etc., we estimate a data entry person can complete 4 records an hour. Five thousand (5,000) records would require approximately 1250 hours. Again, this budget allocation supports data entry staff time, plus training and supervision.

Finally, we charge a hosting fee of **$2200**/year to help defer hosting costs, and to keep security measures and certifications current.

Fees for subsequent years will vary based on the volume of additional cases.

Please note that this estimate does not cover effort involved in the creation or operation (to the extent to which DMU staff are involved) of a Data Use Committee to regulate the dissemination of data for appropriate research; creation and distribution of data sets for analysis to researchers approved by the Data Use Committee; expansion of the database to include additional clinical variables or calculated values not included in the original data abstraction; clinical advice or guidance; or additional interfaces or data access not specified in this scope.

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